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October 31, 2003

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Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Re: U.S. Utility Patent Application  
Appl. No. 10/630,814; Filed: July 31, 2003  
For: **Aryl Substituted Hydantoin Compounds and Their Use as Sodium  
Channel Blockers**  
Inventors: Sun *et al.*  
Our Ref: 1861.1450001/JMC/JSL

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Information Disclosure Statement;
2. PTO-Form 1449 citing documents (AA1-AE1, AL1, AL2, AM1-AP1, AR1-AR11, AS1-AS11, AT1-AT10);
3. Copies of documents cited on PTO-Form 1449; and
4. Return postcard.

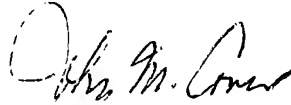
It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Commissioner for Patents  
October 31, 2003  
Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



John M. Covert  
Attorney for Applicants  
Registration No. 38,759

JMC/JSL/asl  
Enclosures

SKGF\_DC1:191861.1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



In re application of:

Sun *et al.*

Appl. No. 10/630,814

Filed: July 31, 2003

For: **Aryl Substituted Hydantoin  
Compounds and Their Use  
as Sodium Channel Blockers**

Confirmation No. *To be assigned*

Art Unit: *To be assigned*

Examiner: *To be assigned*

Atty. Docket: 1861.1450001/JMC/JSL

**Information Disclosure Statement**

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. A copy of each document is also provided.

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned representative submits the following, in regards to non-English language documents **AL1**, **AM1**, **AN1**, **AO1**, **AL2**, **AR9** and **AS9** cited on Form PTO 1449:

Document **AL1**, German Patent Publication No. DT 23 58 504 A1, is in the German language. Document **AM1**, Dutch Patent Publication No. NL 7316064, is in the Dutch language. An English language abstract of both document **AL1** and document **AM1** is attached as document **AS10**

Document **AN1**, German Patent Publication No. DT 24 31 071 A1, is in the German language. An English language abstract of document **AN1** is attached as document **AT10**.

Document **AO1**, World Patent Publication No. WO 95/29910, is in the Japanese language. An English language abstract of document **AO1** is attached as document **AT9**.

Document **AL2**, World Patent Publication No. WO 99/60015, is in the German language. An English language abstract of document **AL2** is attached as document **AR10**.

Document **AR9** is in the Russian language. An English language abstract of document **AR9** is attached as document **AR11**.

Document **AS9** is in the Russian language. An English language abstract of document **AS9** is attached as document **AS11**.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

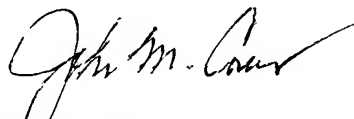
This Information Disclosure Statement is being filed within three months of the date of filing of a national application. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



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Attorney for Applicants  
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Date: OCT 31, 2003

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FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. 1861.1450001/JMC/JSL	APPLICATION NO. 10/630,814
	APPLICANT Sun et al.	
	FILING DATE July 31, 2003	GROUP To be assigned

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA1	3,903,053	09/02/1975	Iwata et al.			11/20/1973
	AB1	5,276,049	01/04/1994	Himmelsbach et al.			03/11/1992
	AC1	5,478,942	12/26/1995	Himmelsbach et al.			10/28/1993
	AD1	5,650,424	07/22/1997	Himmelsbach et al.			08/29/1995
	AE1	5,852,192	12/22/1998	Himmelsbach et al.			05/01/1997
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## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL1	DE 23 58 504 A1	11/22/1973	Germany			Yes X No
	AM1	NL 7316064	11/23/1973	Netherlands			Yes X No
	AN1	DE 24 31 071 A1	01/15/1976	Germany			Yes X No
	AO1	WO 95/29910	11/09/1995	PCT			Yes X No
	AP1	WO 99/05117	02/04/1999	PCT			Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>1</u>	Bensimon, G., et al., "A Controlled Trial of Riluzole in Amyotrophic Lateral Sclerosis," <i>New Engl. J. Med.</i> 330:585-591, Massachusetts Medical Society (1994)
	AS	<u>1</u>	Brown, C.M., et al., "Neuroprotective properties of lifarizine compared with those of other agents in a mouse model of focal cerebral ischaemia," <i>British J. Pharmacol.</i> 115:1425-1432, Stockton Press (1995)
	AT	<u>1</u>	Buchan, A.M., et al., "AMPA Antagonists: Do They Hold More Promise for Clinical Stroke Trials Than NMDA Antagonists?" <i>Stroke Suppl.</i> 24:148-152, Williams and Wilkins (1993)

EXAMINER	DATE CONSIDERED
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.



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FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL2	WO 99/60015	11/25/1999	PCT			Yes X No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
AR	2	Catterall, W.A., "Common modes of drug action on NA <sup>+</sup> channels: local anesthetics, antiarrhythmics and anticonvulsants," <i>Trends Pharmacol. Sci.</i> 8:57-65, Elsevier Science Publishers (1987)	
AS	2	Catterall, W.A., "Structure and Function of Voltage-Sensitive Ion Channels," <i>Science</i> 242:50-61, American Association for the Advancement of Science (1988)	
AT	2	Catterall, W.A., "Neurotoxins that Act on Voltage-Sensitive Channels in Excitable Membranes," <i>Ann. Rev. Pharmacol. Toxicol.</i> 20:15-43, Annual Reviews, Inc. (1980)	

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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	3	Creveling, C.R., et al., "Batrachotoxin-Induced Depolarization and [ <sup>3</sup> H]Batrachotoxinin-A 20 $\alpha$ -Benzoate Binding in a Vesicular Preparation from Guinea Pig Cerebral Cortex," <i>Mol. Pharmacol.</i> 23:350-358, The American Society for Pharmacology and Experimental Therapeutics (1983)
AS	3	Denicoff, K.D., et al., "Efficacy of Carbamazepine Compared With Other Agents: A Clinical Practice Survey," <i>J. Clin. Psychiatry</i> 55:70-76, Physicians Postgraduate Press (1994)
AT	3	Donaldson, I., "Tegretol: A double blind trial in tinnitus," <i>J. Laryngol. Otol.</i> 95:947-951, The Invicta Press (1981)

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	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	<u>4</u>	Graham, S.H., et al., "A Dose-Response Study of Neuroprotection Using the AMPA Antagonist NBQX in Rat Focal Cerebral Ischemia," <i>J. Pharmacol. Exp. Therap.</i> 276:1-4, The American Society for Pharmacology and Experimental Therapeutics (1996)
AS	<u>4</u>	Graham, S.H., et al., "Neuroprotective Effects of a Use-Dependent Blocker of Voltage-Dependent Sodium Channels, BW619C89, in Rat Middle Cerebral Artery Occlusion," <i>J. Pharmacol. Exp. Ther.</i> 269:854-859, The American Society for Pharmacology and Experimental Therapeutics (1994)
AT	<u>4</u>	Hunskaar, S., et al., "Formalin test in mice, a useful technique for evaluating mild analgesics," <i>J. Neurosci. Methods</i> 14: 69-76, Elsevier Science Publishers (1985)

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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>5</u>	Iwasaki, Y., et al., "CNQX prevents spinal motor neuron death following sciatic nerve transaction in newborn rats," <i>J. Neuro Sci.</i> 134:21-25, Elsevier Science (1995)
	AS	<u>5</u>	Majumdar, B., et al., "An electrocochleographic study of the effects of lignocaine on patients with tinnitus," <i>Clin. Otolaryngol.</i> 8:175-180, Blackwell Scientific Publications (1983)
	AT	<u>5</u>	Moller, A.R., "Similarities Between Chronic Pain and Tinnitus," <i>Am. J. Otol.</i> 18:577-585, American Journal of Otolaryngology, Inc. (1997)

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	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>6</u>	Ohizumi, Y., "Specific Inhibition of [ <sup>3</sup> H] Saxitoxin Binding to Skeletal Muscle Sodium Channels by Geographutoxin II, a Polypeptide Channel Blocker," <i>J. Biol. Chem.</i> 261:6149-6152, The American Society of Biological Chemists, Inc. (1986)
	AS	<u>6</u>	Patton, T.L., "Poly(iminoimidazolidinediones) and Poly(parabanic acids)," <i>Polym. Prepr., Amer. Chem. Soc., Div. Polym. Chem.</i> 12:162-8, Division of Polymer Chemistry, American Chemical Society (1971)
	AT	<u>6</u>	Sheardown, M.J., et al., "AMPA, but not NMDA, receptor antagonism is neuroprotective in gerbil global ischaemia, even when delayed 24 h," <i>Eur. J. Pharmacol.</i> 236:347-353, Elsevier Science Publishers (1993)

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	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
AR	7	Simpson, J.J., and Davies, W.E., "Recent advances in the pharmacological treatment of tinnitus," <i>TIPS</i> . 20:12-18, Elsevier Science (1999)	
AS	7	Stys, P.K., et al., "Ionic Mechanisms of Anoxic Injury in Mammalian CNS White Matter: Role of Na <sup>+</sup> Channels and Na <sup>+</sup> -Ca <sup>2+</sup> Exchanger," <i>J. Neurosci.</i> 12:430-439, Society for Neuroscience (1992)	
AT	7	Taylor, C.P., and Meldrum, B.S., "Na <sup>+</sup> channels as targets for neuroprotective drugs," <i>Trends Pharmacol. Sci.</i> 16:309-316, Elsevier Science Ltd. (1995)	

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	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>8</u>	Tonndorf, J., "The analogy between tinnitus and pain: A suggestion for a physiological basis of chronic tinnitus," <i>Hear. Res.</i> 28:271-275, Elsevier Science Publishers (1987)
	AS	<u>8</u>	Woodward, R.M., et al., "Effects of Steroids on $\gamma$ -Aminobutyric Acid Receptors Expressed in <i>Xenopus</i> Oocytes by Poly(A) <sup>+</sup> RNA from Mammalian Brain and Retina," <i>Mol. Pharmacol.</i> 41:89-103, The American Society for Pharmacology and Experimental Therapeutics (1992)
	AT	<u>8</u>	Wrathall, J.R., et al., "Amelioration of Functional Deficits from Spinal Cord Trauma with Systemically Administered NBQX, an Antagonist of Non-N-methyl-D-aspartate receptors," <i>Exp. Neurology</i> 137:119-126, Academic Press, Inc. (1996)

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## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	9	Комон, М.М., et al., "Синтез, Свойства И Превращения Полигидантоинов," Высокомолекулярные Соединения, Серия (А) 18:2092-2096, Chemical Abstract Service (1976)
	AS	9	Трезбоб, В.В., И Шеджаеба, В.Г., "Синтез Полиэфиромочевин И Полигидантоинов В Растворе," Высокомолекулярные Соединения, Серия (В) 13:832-837, Chemical Abstract Service (1971)
	AT	9	English language abstract of WO 95/29910, Derwent World Patents Index (Dialog File 351), WPI Accession No. 10502515

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	AO						Yes No
	AP						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

AR	<u>10</u>	English language abstract of WO 99/60015, Derwent World Patents Index (Dialog File 351), WPI Accession No. 12852717
AS	<u>10</u>	English language abstract of DE 23 58 504 A1 and NL 7316064, Derwent World Patents Index (Dialog File 351), WPI Accession No. 1388171
AT	<u>10</u>	English language abstract of DE 24 31 071 A1, Derwent World Patents Index (Dialog File 351), WPI Accession No. 1569484

EXAMINER

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INFORMATION DISCLOSURE STATEMENTATTY. DOCKET NO.  
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July 31, 2003GROUP  
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## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA						
	AB						
	AC						
	AD						
	AE						
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>11</u>	English language abstract of Комон, М.М., et al., "Синтез, Свойства И Превращения Полигидантоинов," <i>Высокомолекулярные Соединения, Серия (A)</i> 18:2092-2096, Chemical Abstract Service (1976), STNEasy, Database Caplus, Accession No. 1977:6007
	AS	<u>11</u>	English language abstract of Трезбоб, В.В., И Шеджаева, В.Г., "Синтез Полиэфиромочевин И Полигидантоинов В Растворе," <i>Высокомолекулярные Соединения, Серия (B)</i> 13:832-837, Chemical Abstract Service (1971), STNEasy, Database Caplus, Accession No. 1972:113577
	AT		

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